

REMARKS

Claims 1, 2, 4-30, and 32-71 are all of the pending claims. By this amendment, claim 31 has been canceled.

Claims 1, 20, 25, 39, 46, and 53 are independent claims.

Objection to the Specification

Applicant respectfully thanks the Examiner for setting out the objections in a very helpful clear and detailed manner.

With respect to the objections to the specification and assertion that there is no proper antecedent basis for the claimed subject matter, claim 31 has been deleted, and claims 32, 44, 51, 58 and 59 have been amended to claim the ranges as stated in text in the specification. In view of these amendments, Applicant respectfully requests the Examiner to withdraw the objection.

Claim Rejection Under 35 U.S.C. § 112

Claims 39 and 65 are rejected under 35 U.S.C. § 112, second paragraph.

Applicant has amended claim 39 so that it does not include the word “several.” A similar amendment has been made to claim 40.

With respect to claim 65, this claim has been amended to recite “containing casein glycol-macro-peptide”, which the Applicant considers a definite and clear term.

In view of the above, Applicant respectfully requests the Examiner to withdraw the rejections under 35 U.S.C. § 112.

Claim Rejection Under 35 U.S.C. § 102 and 103

Claims 1, 2, 4, 12, 14-19, 23-34, 36, 37, 39-41, 43, 44, and 71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Beringer et al (US 4,139,589).

Claims 5-7, 13, 20-22, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer.

Claims 8-10 and 55-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer in view of Cherukuri (US 4,753,805).

Claims 11, 38, and 45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer in view of Fisher et al. (US 4,370,350).

Claims 46-52 and 54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer in view of Cherukuri, and further in view of Fisher.

Independent Claim 1

Independent claims 1 has been amended to recite:

first integral part comprising a compressed mixture of particulated gum base material and *separate* particulated tablet base material.

As described in the specification with respect to the exemplary embodiments at the 4th paragraph of page 6, the basic principle applied in the gum sweet of claim 1, is one of compression where the die is filled with powder and compressed. As is further described in the paragraph spanning pages 7 and 8, the first layer integral part is filled into the die and compressed and the pressure maintained on the powder for a dwell time to bond the particles together and compact them to form the compressed first layer. The mixture of gum base and

tablet material is thus exemplified as being in particulate form when compressed, without any intermediate blending into a coherent mass and a subsequent disintegration into particulate form. The process described on top of page 6 also describes a mixing of particulated material and subsequent feeding of the mixture to the tablet press where the particulated materials are compressed.

Applicant respectfully requests the Examiner to withdraw the rejection of independent claim 1 at least because Beringer does not disclose or suggest the chewing gum sweet including the first integral part comprising a compressed mixture of particulated gum base material and separate particulated tablet base material.

In the response to arguments in item 41 of the Official Action, the Examiner asserts that the teachings of Beringer are taken to indicate a compressed mixture of particulated gum base material and particulated tablet base material. Applicants respectfully disagrees.

In Beringer, the gum base and tablet base materials are formed as *a common, blended mass in a traditional manner*. The result is that tablet base material is united with the gum base to form a chewing gum mass that is particulated. In this particulated material it is no longer possible to discern gum base material from tablet base material, as they have together formed chewing gum mass. When the chewing gum mass of Beringer is particulated, the result is not a particulated gum base material and a particulated tablet base material, but instead *a combined particulated gum material*.

There is no disclosure in Beringer et al. of the granulated gum being combined with tablet base granules prior to compression. In stead, any material that could possibly be identified as a tablet base material has previously been included in the material together with the plastic mass

referred to in Beringer in an intimately mixed homogenous form, where the tablet material has changed form and become part of the common resulting material, which resulting material has been granulated. In the particulated material utilized according to Beringer for layered tablets no longer have tablet material as such in the particles but instead the resulting material is homogenous.

That is, in Beringer, the desire is to provide a medicated gum composition which allows controlled and variable release of different pharmaceutical ingredients placed in different zones of its compositions (see lines 38-47 in column 1). The homogenous material in the first part of Beringer is in distinct contrast to the recited layer of the first part composed of a compressed mixture of particles of tablet base material and particles of gum material. The particles of tablet base material are present in the first part, also after the compression, as this is a direct consequence of the presence of the particles of tablet base material when compressing.

When a tablet material is mixed with the gum base material into a homogenous material prior to being particulated and compressed – like that disclosed in Beringer – then all particles in the first part will be of the same kind and of uniform material. On the other hand, when particulated gum base material and particulated tablet base material are mixed and then compressed as a mixture of particulated materials, then the particulate tablet base material will be present in between and separate from particulate gum material in the first part of the tablet after the compression, and thus be present in the tablets.

In addition, the attachment, **Experimental Test Report HE4** clearly shows that the above feature results in a surprising technical advantage: improved crunchiness. Specifically, as can be seen from Figure 1.3.1 of the experimental report HE4, the hardness of the gum part of

the chewing gum tablet (which hardness is an indicator of crunchiness) is in the preferred range 200-300 N when using a chewing gum tablet composition in accordance with the sweet of claim 1. However, when modifying the composition of Example 1 only by pre-forming chewing gum particles for compression to form the gum part of the chewing gum tablet, a decrease in hardness of the chewing gum layer is observed so that the hardness falls below 100 N. This is indicative of improved crunchiness of the gum part of the chewing gum tablet when following the teaching of claim 1 to compress two different particle types, namely gum base particles and tablet base particles to form the gum part, as opposed to compress pre-formed chewing gum particles to form a gum part.

Figure 1.3.2 of part one of the experimental report further shows that the crunchiness of the tablet part is greater when making use of the present invention, a crunchiness of nearly 10 dB being obtained as compared to a crunchiness of only about 2 dB when pre-paring a chewing gum tablet including a gum part formed from uniform chewing gum particles.

The data shown in the above figures leads to the conclusion that an overall improvement in crunchiness is associated with the use of two different types of particles (i.e. gum base particles and tablet base particles) for preparation of the gum part, as compared to the use of pre-formed chewing gum particles. This expectation based on analytical measurement methods of crunchiness of the two component parts of the chewing gum tablet (hardness of the gum part and crunch loudness of the tablet part) is corroborated by the data in Figure 1.3.3 of the experimental report HE4, which shows a sensorial evaluation of crunchiness of two chewing gum tablets as a whole. As can be understood from part one of the test report as a whole and in particular from the bar chart in Figure 1.3.3, sensorial judges found the chewing gum tablet of example 1 (i.e. the

example in accordance with the present invention) to be much more crunchy than the chewing gum tablet of comparative example 1 which differed only in that just one type of particles, i.e. chewing gum particles, were compressed to form the gum part of the chewing gum tablet.

Thus, Applicant respectfully requests the Examiner to withdraw the rejection of independent claim 1.

Independent Claims 20, 25, 39, and 46

Applicant has also amended independent claims 20, 25, 39, and 46 in a similar manner to independent claim 1.

Claim 20 recites a process for preparation of a chewing gum sweet that includes:

forming a first integral part of particulated gum base material and *separate* particulated tablet base material by mixing a particulated gum base material with a particulated tablet base material;

Claim 25 recites that the claimed chewing gum sweet includes:

a first integral part comprises a compressed mixture of particulated gum base material and *separate* particulated tablet base material.

Claim 39 recites that the chewing gum sweet includes:

at least one layer [that] comprises a compressed mixture of particulated gum base material and *separated* particulated tablet base material and at least another layer [that] comprises compressed tablet base material.

Claim 46 recites that the chewing gun sweet includes:

at least one layer [that] comprises compressed particulated gum material and *separated* particulated tablet base material.

Applicant respectfully submits that these claims are patentable at least because Beringer does not disclose the separate particulated gum base material and tablet base material, as discussed above with respect to claim 1.

Independent Claim 53

Independent claim 53, as currently amended, includes the feature that:

the different colors of the layers provide contrasting effects to give a distinctive visual indication of the at least two layers.

The contrasting effects and the distinctive visual indication of the gum layer with respect to the other layer in the tablet may signal high quality of the tablet. The materials of the first and second integral parts of the tablet are in contact, and if the tablet should be subjected to inappropriate treatment, such as wrong storing conditions, then substances may migrate from one part of the chewing gum tablet to another.

If substances migrate due to inappropriate treatment of the tablet in the period between manufacturing and packaging and the actual sale to the customer or chewing of the tablet by the consumer, the migrating substances will cause the color to also migrate, thus blurring the transition between the different parts of the chewing gum tablet and giving a visual indication of the degree of migration. The less distinct the contrast between the parts of the chewing gum tablet, the greater the deterioration.

Applicant respectfully requests the Examiner to withdraw the rejection of independent claim 53 because the recited distinct coloring of the layers is not disclosed in Beringer. Moreover, there would be no need for such an effect in Beringer as the thin chicle layer acts as a barrier layer in the tablet of Beringer.

Thus, Applicant respectfully requests the Examiner to withdraw the rejection of independent claim 53.

Dependent Claims

Applicant respectfully requests the Examiner to withdraw the rejection of dependent claims 2, 4-7, 12-19, 20-24, 26-37, 40-44, and 71 at least because of their dependency.

Applicant respectfully requests the Examiner to withdraw the rejection of dependent claims 8-10, 53, and 55-70 at least because of their dependency and for the reasons discussed below. In Beringer, the disclosed content of chicle of less than 1% of the weight of the tablet is too low to produce anything but a barrier layer. When the examples of Beringer are followed the resulting tablet does not have an integral part of chewing gum, but only a barrier layer with chicle interposed between integral parts of pure tablet material.

Cherukuri discloses the compression of a tablet having a single integral part, and Applicant respectfully submits *that one of ordinary skill would not have combined* Beringer and Cheruki because Beringer only discloses such a small amount of gum material, used as a barrier layer, that the teaching of Cheruki of making a chewing gum tablet with a single integral part does not combine with the teaching of Beringer.

Applicant respectfully requests the Examiner to withdraw the rejection of dependent claims 11, 38, and 45 at least because of their dependency and because Fisher does not make up for the deficiencies discussed above.

Applicant respectfully requests the Examiner to withdraw the rejection of dependent claims 46-52 and 54 at least because of their dependency and because neither Cherukuri nor Fisher makes up for the deficiencies discussed above.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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